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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,861	02/23/2004	Gilbert S. Laroya	002-C1	9437

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EXAMINER	
SMITH, FANGEMONIQUE A	
ART UNIT	PAPER NUMBER
3736	
MAIL DATE	DELIVERY MODE
07/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/784,861	LAROYA ET AL.	
	Examiner	Art Unit	
	FANGEMONIQUE SMITH	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 17-19 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 17 recites the limitation "a first end of the guide member" in lines 1 and 2. Prior to recitation of this limitation, a first end of a guide member is disclosed in claim 16, a claim from which claim 17 depends. It is unclear whether the limitation refers to the first end of the guide member previously disclosed or if the limitation intends to introduce another first end of the guide member, rendering the claim indefinite. Upon rejection of claim 17, any claim depending from claim 17 is also rejected.

5. At line 3 of claim 29, the pronoun "its" is used. However, one cannot be certain to what the pronoun is intended to refer. Hence, the claim is rendered unclear and indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 8, 9, 16-18, 20-28 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Swartz et al. (U.S. Patent Number 5,715,818).

In regard to claims 1, 2, 8, 9, 16-18, 20-28 and 30-32, Swartz et al. disclose a system for placing a guide member through the wall of a patient's heart so that the guide member extends through a coronary vessel and the wall of the heart into the left atrium of the patient's heart (Abstract; col. 1, lines 63-67; col. 2, lines 1-30). The system comprises an introducer sized and configured for placement through a coronary vessel and the wall of a patient's heart into a heart chamber and a guide member sized and configured to be positioned in the introducer and placed through the coronary vessel and the heart wall into the heart chamber (Figure 2).

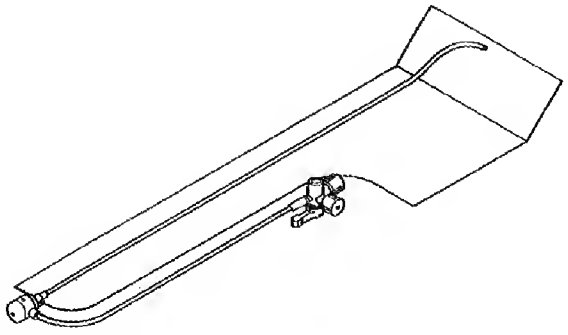
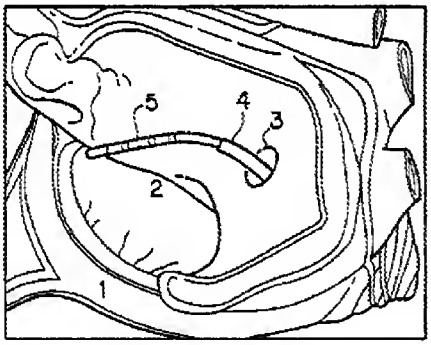


FIG. 4

The guide member disclosed by Swartz et al. has a proximal portion adapted to remain outside the heart and a distal portion adapted to be passed into and then back out of the heart chamber. As the guide member of the Swartz et al. device is passed through the introducer and moves through the coronary vessel and the heart wall to a location within the heart chamber. Figure 4 shows the device and the controller mechanism which is located at the proximal portion of the device. The introducer is a hollow sleeve which receives a guide wire. Swartz discloses passing the distal end of the guide wire through the introducer into the heart chamber (Figure 2).

SHEATH & CATHETER
IN
LEFT ATRIUM



1. CORONARY SINUS
2. MITRAL VALVE
3. FOSSA OVALIS (PATENT)
4. SHEATH
5. CATHETER

FIG. 2

Swartz et al. discloses the introducer of the system and the guide member being configured to direct the distal portion of the guide member to a predetermined location within the heart chamber upon introducing the guide member into the chamber (col. 7, lines 17-45). The guide member is configured for delivery to an internal surface of the left atrium as disclosed by Swartz

et al. Upon use of the Swartz et al. system, the device is placed in a patient's heart extending the guide wire through a coronary vessel (col. 6, lines 34-67; col. 7, lines 1-16). The guide wire is further extended into a heart chamber containing blood and then passed back out the heart chamber (col. 3, lines 44-67; col. 6, lines 8-62).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 3-7, 10-12, 14, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al. (U.S. Patent Number 5,715,818) in view of Cope et al. (U.S. Patent Number 5,776,079).

In regard to claims 3-7, 10-12, 14, 15 and 19, Swartz et al. disclose the features of the Applicant's invention as described above. Swartz et al. do not disclose having a snare device adapted to grasp and pull the guide member out of the heart chamber. Cope et al. discloses a catheterization apparatus which includes a catheter which introduces a guide wire into a vessel. The apparatus further includes an inserter sheath engageable with the catheter to facilitate the passage of the guide wire through the catheter (Abstract). Cope et al. also disclose the use of a balloon catheter for accessing a vasculature site of interest. Once the apparatus is introduced into a vessel, Cope et al. teach the use of a snare device in conjunction with the apparatus to remove the apparatus from the vessel in which it is deployed. It would have been obvious to one having

ordinary skill in the art at the time the Applicants' invention was made to modify a system and method for using a guiding introducer, similar to that disclosed by Swartz et al., to include a snare device to retrieve the guide member, similar to that disclosed by Coelho, to provide a mechanism which retrieves the device upon adverse events occurring during use which may lead to problems for the patient (col. 8, lines 58-67; col. 9, lines 1-18).

10. Claims 13 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al. (U.S. Patent Number 5,715,818) in view of Cope et al. (U.S. Patent Number 5,776,079) and in further view of Lau et al. (U.S. Patent Number 6,113,607).

In regard to claims 13 and 29, the combined references of Swartz et al. and Cope et al. disclose the features of the Applicant's invention as described above. The combined references do not specifically disclose a clamp device for locking the delivery device to the guide member. Also, although the combination teaches accessing a site within an internal surface of the heart to perform a procedure, the combined references do not specifically disclose the conduit comprising delivery of a stent. Lau et al. disclose a stent deliver method and system. The system comprises a sheath having an outer lumen and an expandable device. Lau et al. further disclose a catheter disposed within the outer lumen of the sheath. A stent is mounted on the expandable device and upon advancement of the catheter through the vasculature of a patient, the stent is expanded into a position at a desired location (col. 2, lines24-47). Lau et al. disclose having a Luer locking device to secure the balloon delivery device to the catheter (col. 8, lines 1-35). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a system and method for using a guiding introducer, similar to that disclosed by the combined references of Swartz et al. and Cope et al., to include a delivery

device secured to the guide member for delivering a stent, similar to that disclosed by Lau et al., to provide another method for resolving problems detected within the intravascular structures of a patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FANGEMONIQUE SMITH whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736